

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/762,261	QUINNAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey Stucker	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendments filed 9/8/05 and 1/17/06.
2. ☒ The allowed claim(s) is/are 65-72 and 74-94.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>9/11/03</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/ <del>Comment</del>        |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

This Notice of Allowability is in response to the amendments filed 9/8/05 and 1/17/06. Both amendments will be entered. Claims 65-72 and 74-94 are pending and allowable.

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Jeffrey Stucker, Art Unit 1648.

An Examiner's Amendment to the record is attached. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Robert Smyth on 4/5/06.

The following is an Examiner's Statement of Reasons for Allowance:

The amendments obviate the rejections. The prior art does not teach SEQ ID NO:1 or amino acids 313-325 of SEQ ID NO:1, or SEQ ID NO:3. The variation required by "percent sequence identity in the V3 region" of claims 70-72 is read to mean the

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variation is in the V3 region of SEQ ID NO:1 and not in the sequence of amino acids 313-325 of SEQ ID NO:1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



**JEFFREY STUCKER**  
**PRIMARY EXAMINER**

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EXAMINER'S AMENDMENT

65. (Previously Presented) An isolated HIV envelope protein capable of inducing the production of a cross-reactive neutralizing anti-serum against multiple strains of HIV-1 in vitro comprising an amino acid sequence with at least ninety-two (92) percent sequence identity to SEQ ID NO: 1.

66. (Previously Presented) The isolated HIV envelope protein of claim 65 wherein the protein comprises an amino acid sequence with at least ninety-five (95) percent sequence identity to SEQ ID NO: 1.

67. (Previously Presented) The isolated HIV envelope protein of claim 65 wherein the protein comprises an amino acid sequence with at least ninety-eight (98) percent sequence identity to SEQ ID NO: 1.

68. (Previously Presented) The isolated HIV envelope protein of claim 65 wherein the protein comprises an amino acid sequence with at least ninety-nine (99) percent sequence identity to SEQ ID NO: 1.

69. (Currently Amended) An isolated HIV envelope protein capable of inducing the production of a cross-reactive neutralizing anti-serum against multiple strains of HIV-1 in vitro wherein the V3 region of the HIV envelope protein comprises amino acids 313 to 325 of SEQ ID NO: 1.

70. (Previously Presented) The isolated HIV envelope protein of claim 69 wherein the protein comprises an amino acid sequence with at least ninety (90) percent sequence identity in the V3 region of SEQ ID NO: 1.

71. (Previously Presented) The isolated HIV envelope protein of claim 69 wherein the protein comprises an amino acid sequence with at least ninety-five (95) percent sequence identity in the V3 region of SEQ ID NO: 1.

72. (Previously Presented) The isolated HIV envelope protein of claim 69 wherein the protein comprises an amino acid sequence with at least ninety-nine (99) percent sequence identity in the V3 region of SEQ ID NO: 1.

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73. (Cancelled)

74. (Previously Presented) The isolated HIV envelope protein of claim 69 wherein the V3 region comprises the amino acid sequence of SEQ ID NO: 3.

75. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the protein comprises a cyclic peptide.

76. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the protein is at least 95 amino acid residues in length.

77. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the HIV envelope protein is recombinantly produced.

78. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the protein is glycosylated at one or more amino acid residues.

79. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the HIV envelope protein is synthetically produced.

80. (Previously Presented) The isolated HIV envelope protein of claim 65 or 69 wherein the protein is linked to a second protein.

81. (Previously Presented) The isolated HIV envelope protein of claim 80 wherein the protein is linked to the second protein by a peptide linker.

82. (Previously Presented) An isolated HIV envelope protein comprising the amino acid sequence of SEQ ID NO: 1.

83. (Previously Presented) An isolated HIV envelope protein consisting of the amino acid sequence of SEQ ID NO: 1.

84. (Previously Presented) A composition comprising an isolated HIV-1 envelope protein of any one of claims 65, 69, 82 or 83 and a pharmaceutically acceptable carrier.

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85. (Previously Presented) The composition of claim 84 further comprising an adjuvant.

86. (Previously Presented) The composition of claim 84 wherein the composition is suitable for use in humans.

87. (Previously Presented) A method of generating antibodies in a mammal comprising administering the composition of claim 84.

88. (Previously Presented) A method of generating antibodies in a mammal comprising administering the isolated HIV-1 envelope protein of claim 65 or 69.

89. (Previously Presented) The method of claim 88 wherein the mammal is a human.

90. (Previously Presented) The method of claim 88 wherein the antibodies produced are monoclonal.

91. (Previously Presented) The method of claim 90 wherein the mammal is a mouse.

92. (Previously Presented) The method of claim 90 further comprising humanizing the monoclonal antibody.

93. (Previously Presented) The method of claim 88 wherein the antibodies produced are polyclonal.

94. (Previously Presented) The method of claim 88 wherein the mammal is a primate.